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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,659	04/08/2004	Gregory S. Kelley	1001.1755101	8007

28075 7590 06/20/2008

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ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
06/20/2008	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/820,659
Filing Date: April 08, 2004
Appellant(s): KELLEY, GREGORY S.

Gregory S. Kelley
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 4/07/2008 appealing from the Office action mailed 7/30/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US2004/0064129 DENIEGA et al. 04-2004

US2001/0026666	FERRERA et al.	10-2001
US2001/0020161	KLIMA et al.	09-2001
US2003/0077423	FLANIGAN et al.	04-2003
USPN6,180,544	JAUCHEN et al.	01-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 and 7 stand rejected under 35 U.S.C. 102(e) as being anticipated by Deniega et al. (US2004/0064129). Deniega et al. discloses a catheter for uniform delivery of medication.

Regarding claims 1-4 and 7, Deniega et al. discloses a medical device (278) (Figures 25-26a) comprising a first component (282) having an outer surface (near 285) including an outer engagement portions, a second component (280) having an inner surface (near 281) including an inner engagement portion (near 286) wherein the inner engagement portion configured to fit over the outer engagement portion and an aerated adhesive layer ([0107-0109]) positioned between the inner engagement portion and the outer engagement portion (see figure 26A). Examiner asserts that Deniega et al. discloses a biocompatible medical glue adhesive that will inherently (unless assembled in a completed vacuum, which is not disclosed in Deniega et al.) have some air voids present during the manufacture and assembly of the two components (280, 282) and therefore meets the broadest reasonable definition of an aerated adhesive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-6 stand rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. (US2001/002666). Deniega et al. meets the claim limitations as described above except a light curable epoxy aerated adhesive.

However, Ferrera et al. teaches a variable stiffness optical fiber shaft.

Regarding claims 5-6, Ferrera et al. teaches tubular medical device (Figures 1-7) comprising several components that are assembled with light curable epoxy adhesive ([0014]).

At the time of the invention, it would have been obvious to use the adhesive of Ferrera et al. to assemble the catheter of Deniega et al. because the light curable adhesive allows for increased joining flexibility and ease of manufacturing because of the ability to spread and fully the light adhesive. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Ferrera et al. ([0007-0022]).

Claims 8 and 13 stand rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. (US2001/002666). The modified Deniega et al. meets the claim limitations except for the specific voids and densities.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the aerated-adhesive with the void space and density as claimed by Applicant for optimal joining performance and gap space, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)*.

Claims 9-12 stand rejected under 35 U.S.C 103(a) as being unpatentable over in Deniega et al. in view of Jauchen et al. (6,180,544). Deniega et al. meets the claim limitations as described above except for the specific voids filled with inert N2 gas and various pressures.

However, Jauchen et al. teaches an air-permeable substrate material with a self-adhesive coating process for its production and its use.

Regarding claims 9-12, Jauchen et al. teaches the use of foamed adhesives which are used in the process of assembling medical devices (bandages). During the process that uses various noble gases (N2) and discusses various pressure and joining temperatures (cols 1-2).

At the time of the invention, it would have been obvious to use the adhesive of Jauchen et al. with the catheter of Deniega et al. because the adhesive allows for improved joining and adhesive flexibility between joined

parts. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Jauchen et al. (cols 1-2).

Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the adhesive at the specific pressure, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)*.

Claims 14-15 are rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. Deniega et el. meets the claim limitations as described above except for the specific adhesive layer thickness.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the adhesive layer to desired thickness for optimal joining and reliability, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

Claims 16-18 stand rejected under 35 U.S.C 103(a) as being unpatentable over Deniega et al. in view of Klima et al. (US2001/0020161). Deniega et al. meets the claim limitations as described above except for the specific catheter components.

However, Klima et al. teaches a catheter support structure.

Regarding claims 16-18, Klima et al. teaches a catheter with a hub (12), strain relief (22), and elongate shaft (20) (see Figure 1).

At the time of the invention, it would have been obvious to incorporate the strain relief and hub of Klima et al. to the system of Deniega et al. in order to increase catheter reliability and add strain control to the end of the catheter to prevent kinking. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Klima et al. ([0001-0010]).

(10) Response to Argument

Applicant's first argument is directed towards the rejection under 35 U.S.C. 102(e) as being anticipated by Deniega et al. (US2004/0064129). Applicant argues that the Deniega et al. reference does not disclose the **aerated adhesive layer** (52) as shown is Applicant's figure reproduced below. Applicant asserts that definition of the aerated adhesive layer is given in Applicant's specification page 11, ln 2-17.

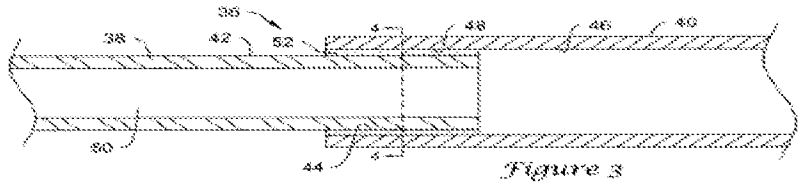
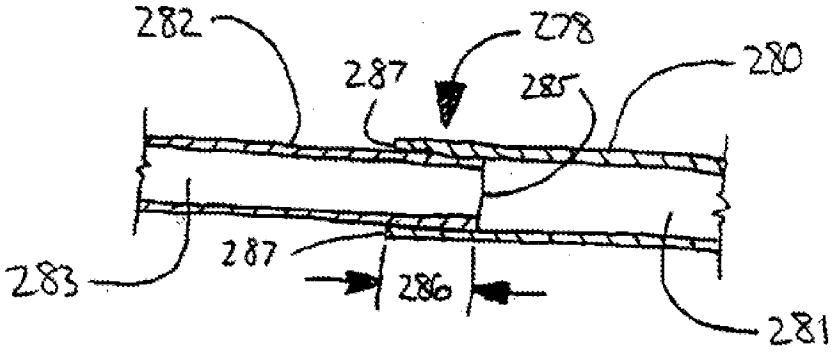


Figure 3

Applicant further argues that Deniega et al. does not disclose an adhesive that would inherently resist delamination, absorb stress, comprise distensible regions, and comprise voids.

It is Examiner's position that the Deniega et al. reference discloses the claimed limitation of two medical components joined by an **aerated adhesive** (see Figure reproduced below).



Applicant attempts to define the term “aerated adhesive” by the process of forming disclosed in the specification page, 11 ln 2-17. Examiner asserts that this is not a definition, it is a non-specific process of making several embodiments of the invention and lacks the words "only, must, or specifically" which are commonly used to define specific terms and add precision to the terms as generally used when Applicant becomes their own lexicographer. Therefore the Examiner applies the broadest reasonable definition of the term "aerated adhesive" in which the adhesive has at least some air space within the bond. As described above the Examiner asserts that during the bonding process it is known that air bubbles are present during manufacture, it is also well known that very unique applications where air bubbles are to be avoided the manufacture is done underneath a complete vacuum to remove dissolved air that is present within the adhesive or any air that could enter during the curing process.

Applicant furthers attempts to define the term "aerated adhesive" as having a plurality of voids.

Examiner makes note that limitation of voids is in a dependant claim, not the independent claim; therefore by Applicant's own claim drafting, the term “aerated adhesive” does not even require void spaces since a subsequent claim adds this narrowing feature. Finally Applicant contends that the biocompatible medical glue of Deniega et al. does not meet the characteristics of resisting delamination, absorbing stress, and comprising distensible regions; Examiner asserts that these are well known common characteristics of adhesive glues.

Applicant’s subsequent argument’s are directed towards the rejection under 35 U.S.C 103(a) as being unpatentable over Deniega et al. in view of Ferrera et al. (US2001/002666) or Deniega et al. in view of Jauchen et al. (6,180,544) or Deniega et al. in view of Klima et al. (US2001/0020161). **Applicant argues that the combination of Deniega et al. with the secondary references in not proper because one of ordinary skill in the art would have not combined the references as claimed and that they are non-analogous with the instant invention.**

Examiner asserts that the combination of the Deniega et al. reference with the secondary references above are proper. Examiner asserts that the one of ordinary skill would recognize that the devices of the references are analogous in the field of endeavor of medical devices (bandages, catheter optical fiber) and the adhesives used to secure and manufacture them; and thus meets the test required for 103 U.S.C. 103(a). Examiner also asserts that one of ordinary skill

in art would apply the adhesive bonding techniques of all medical devices as described in the references in order to attain the best possible bond between medical device components while maintaining a safe, effective, biocompatible device.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Christopher D Koharski/

Examiner, Art Unit 3763

Conferees:

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763

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